



Program Evaluation of the Centers of Excellence in Regulatory Science and Innovation (CERSIs)

Charge to Subcommittee of the Science Board to FDA

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What are the CERSIs?

FDA's Centers of Excellence in Regulatory Science and Innovation (CERSIs) are:

joint efforts between FDA and academic institutions to work collaboratively on projects that promote regulatory science, including innovative research, education, and scientific exchange under a cooperative agreement grant (U01).

Currently, there are four CERSIs in operation:

- ▶ University of Maryland (UMD)
- ▶ Georgetown University (GU)
- ▶ Johns Hopkins University (JHU)
- ▶ UC-San Francisco (UCSF) & Stanford University

CERSI Overall Goals

Address scientific challenges arising from new medical product development, regulatory activities, and the need to improve food safety and quality

Collaboration with academic partners on research that supports FDA's regulatory mission & improves public health

Support training needs for FDA, new scientists, & scientific community

Enhance extramural partnerships and expand scientific exchanges

CERSI Research Projects - examples

University of Maryland:

- ▶ Membrane Transporters in Mediating Drug-Drug Interactions (w/ CDER)
- ▶ Development of Bioengineering standards (w/ CDRH)
- ▶ Harnessing Diverse Data with CDER Safe Use Initiative (w/ CDER)
- ▶ Minority Health Focused Research (w/ OMH)



Georgetown University:

- ▶ Evaluation of Pharmacogenomic markers of drug response
- ▶ Genetics of autoimmune diseases for vaccine safety
- ▶ Minority health: Health and science literacy (focus groups)
- ▶ Voluntary data sharing of biomedical research data



CERSI Educational/Training Projects

University of Maryland - features:



- ▶ MS in Regulatory Science – UMB (online) and MEng in Regulatory Science and Engineering – UMCP
- ▶ Monthly lectures at White Oak (with CMEs) and workshops
- ▶ CERSI Days at UMB
- ▶ Accessibility of UMD scientific facilities (e.g., laboratories) to FDA staff

Georgetown University - features:



- ▶ Master of Science in Clinical and Translational Research, Regulatory Science concentration
- ▶ Development of new courses in regulatory science
- ▶ FDA staff can participate in MedStar Health Hospitals Grand Rounds
- ▶ Clinical Privileges for FDA clinicians at MedStar Health hospitals and clinics (soon to be available)

Two New CERSI Cooperative Agreements

University of California-San Francisco (UCSF)-Stanford University:

The UCSF-Stanford CERSI builds on the enormous strengths of UCSF and Stanford University in the quantitative sciences and pharmacology to provide novel education, exchange, and collaborative research programs focusing on:

- ▶ Improving preclinical safety and efficacy tests
- ▶ Improving clinical trials and evaluation
- ▶ Harnessing diverse data sets through information sciences to accelerate and improve new drug development

Johns Hopkins University (JHU):

The Johns Hopkins Krieger School of Arts and Sciences, the Johns Hopkins Bloomberg School of Public Health and the Johns Hopkins School of Medicine will work with FDA staff and scientists on:

- ▶ clinical evaluations
- ▶ social and behavioral science
- ▶ food safety

Why evaluate the CERSIs now?

Independent, objective group can see the big picture

Sufficient time has elapsed to learn from the first two CERSIs:

- ▶ What Works and Lessons Learned
- ▶ Also, learn from experience of other similar Centers and networks

Perfect Timing!

- ▶ 2 CERSIs completed 3-year period; 2 CERSIs are starting work
- ▶ Best time to apply best practices to enhance work of future CERSIs

Overall Evaluation Criteria for CERSI

CERSI and CERSI Network Roles and Functions:


Do the established roles and functions appropriately advance FDA's regulatory science needs and priorities?

CERSI Performance Metrics for Success:

What criteria should be used to measure the overall success and impact for FDA, the academic centers, and other stakeholders?

CERSI Evaluation Components

CERSI Scientific Research Projects

 Research topics and metrics of success

CERSI Education and Training Projects

 Expectations and Needs

CERSI Infrastructure

 Support from FDA and other stakeholders



Q&A and Discussion